

R E M A R K S

Reconsideration of this application, as amended, is respectfully requested.

RE: CLAIMS 1, 3, 4, 7, 10-12, 20 and 21

Claim 1 has been amended to delete the recitations of the features of the present invention whereby the first needle is positioned at an oral side of the holding device before piercing the digestive wall, and whereby the apparatus comprises a suture retaining device having a grasping section adapted to grasp the suture after the suture has passed through the digestive wall.

In addition, claim 1 has been amended to incorporate the feature of the present invention previously recited in allowable claim 6 whereby a second needle positioned beside and spaced apart by a distance from the first needle. Accordingly, it is respectfully submitted that amended claim 1 now recites allowable subject matter.

Still further, claims 7 and 20 have been amended to depend from amended claim 1, and claim 12 has been amended to correct a minor grammatical error.

No new matter has been added, and it is respectfully requested that the amendments to claims 1, 3, 4, 7, 10-12, 20 and 21 be approved and entered.

It is respectfully submitted, moreover, that amended claim 1 and claims 3, 4, 7, 10-12, 20 and 21 depending therefrom are now all in condition for immediate allowance.

RE: NEW CLAIMS 24-31 and CLAIMS 2, 8 AND 9

New claim 24 has been added depending from claim 1 to recite the feature of the present invention previously recited in claim 1 whereby the apparatus comprises a suture retaining device having a grasping section adapted to grasp the suture after the suture has passed through the digestive wall.

In addition, claims 2, 8 and 9 have been amended to depend from new claim 24.

Still further, new claim 25 has been added depending from claim 1 to recite the feature of the present invention whereby a second endoscope and a sheath outside of the second endoscope are provided, and wherein the first needle extends from a distal end of the sheath, as shown in Fig. 28 in which sheaths 111a and 111b are provided externally to the second endoscope 6.

And finally, new claims 26-31 have been added to recite further features relating to the position of the second needle, as shown in Figs. 28-30 and as supported by the disclosure in the specification at paragraphs 66-69.

No new matter has been added, and it is respectfully

requested that the amendments to claims 2, 8 and 9 and the addition of new claims 24-31 be approved and entered.

It is respectfully submitted, moreover, that claims 24-27 depending from claim 1, claims 2, 8 and 9 depending from claim 24, claim 28 depending from claim 11, claim 29 depending from claim 12, claim 30 depending from claim 21, and claim 31 depending from claim 25 are all in condition for immediate allowance based on their dependence from allowable claim 1.

RE: CLAIMS 22 AND 23

Claims 22 and 23 were rejected under 35 USC 112, second paragraph. On page 2 of the Office Action, the Examiner asserts that the recitation of the "an opening through which the first needle extends provided at a position on a handle side of the distal end of the first endoscope" is unclear, because the claimed opening does not appear in Figs. 28-30 and because "handle side" is unclear. In addition, the Examiner asserts that the recitation of the "optical system" in claim 23 is unclear.

Claim 22 has been amended to be placed in independent form. According to the present invention as recited in amended independent claim 22, an apparatus for forming an artificial valve to treat gastroesophageal reflux disease is provided, which comprises an endoscope that has an observation system and that is

adapted to be orally inserted into a body cavity; a holding device extending out of a distal end of the endoscope, the holding device comprising a distal end portion adapted to hold a point of a digestive wall of the body cavity where the artificial valve is to be formed, and an elongated portion that passes through a first channel provided in the endoscope; a first needle that is moveable relative to the endoscope for penetrating the digestive wall; and a suture adapted to pass through the digestive wall following the first needle; wherein the endoscope comprises an elongated insertion section; a handle section; and an opening through which the first needle extends provided at a position on a proximal side of the distal end of the endoscope.

It is respectfully submitted that the opening through which the first needle extends which is provided at a position on a proximal side of the distal end of the endoscope is shown in Fig. 37 and described in the specification at paragraph 80. (See exiting hole 158 provided proximal to the distal end of the endoscope 150.)

In addition, claim 23 has been amended to clarify the feature of the present invention whereby the observation system comprises an optical system provided at each of the distal end and a portion near the opening of the first endoscope, as shown in Fig. 37, and as supported by the disclosure in the

specification at paragraphs 79 and 80. (See optical systems 151 and 152 in Fig. 37.)

No new matter has been added, and it is respectfully submitted that amended claims 22 and 23 are in full compliance with the requirements of 35 USC 112. Accordingly, it is respectfully requested that the amendments to claims 22 and 23 be approved and entered and that the rejection under 35 USC 112 be withdrawn.

It is respectfully submitted, moreover, that the rejection under 35 USC 103 in view of USP 6,352,503 ("Matsui et al") be withdrawn since Matsui et al and the claimed present invention were commonly owned at the time the claimed present invention was made. See 35 USC 103(c).

Nevertheless, it does appear that the 18 month publications of the priority documents of USP 6,352,503 (namely, Japanese Application Publication Nos. JP 2000-033071 and JP 2000-037348 which are submitted herewith in an Information Disclosure Statement) are proper references against the present application under 35 USC 102(a). For this reason, comments distinguishing the present invention as recited in amended claims 22 and 23 over JP 2000-033071 and JP 2000-037348 are provided hereinbelow.

On page 5 of the Office Action, the Examiner argues that treating tool insertion inlet 19 or end faces 38 of Matsui et al

(see JP 2000-033071) correspond to the opening of claim 22. In this connection, it is assumed that the end faces 38 referred to by the Examiner are the unnumbered openings of second tube 36 or third tube 37 of Matsui et al.

It is respectfully pointed out, however, that according to the present invention as recited in amended independent claim 22, the endoscope comprises, in particular, an opening through which the first needle extends provided at a position on a proximal side of the distal end of the endoscope. That is, as shown in Figs. 37-39 and as described in the specification at paragraph 82, the needle 157 extends through hole 158 to pierce the tissue of a patient.

By contrast, according to JP 2000-033071 (as explained in USP 6,352,503) insertion inlet 19 is provided at the proximal operating section 8 of the endoscope to allow a treating tool 3 to be inserted therethrough to emerge from a distal end of the endoscope (column 5, lines 36-44). And in JP 2000-033071 (as explained in USP 6,352,503) second and third tubes 36 and 37 are provided for having leading insertion tools 2, comprising grasping forceps, inserted therethrough. Thus, it is respectfully submitted that insertion inlet 19 and the openings of second and third tubes 36 and 37 of JP 2000-033071 (and USP 6,352,503) do not correspond to an opening through which the

first needle extends, in the manner of the present invention as recited in amended independent claim 22.

In addition, it is respectfully submitted that JP 2000-037348 also does not disclose, teach or suggest an opening through which the first needle extends provided at a position on a proximal side of the distal end of the endoscope, in the manner of the present invention as recited in amended independent claim 22.

It is respectfully submitted, therefore, that amended independent claim 22 and claim 23 depending therefrom clearly patentably distinguish over JP 2000-033071 and JP 2000-037348 under 35 USC 103.

And accordingly, it is respectfully submitted that amended claims 22 and 23 are now also in condition for immediate allowance.

CLAIM FEE

The application as amended now contains 22 claims, of which 2 are independent. Accordingly, a claim fee in the amount of \$36.00 for the addition of 2 extra claims in total is attached hereto. In addition, authorization is hereby given to charge any additional fees which may be determined to be required to Account No. 06-1378.

In view of the foregoing, entry of this Amendment, allowance of the claims and the passing of this application to issue are respectfully solicited.

If the Examiner has any comments, questions, objections or recommendations, the Examiner is invited to telephone the undersigned at the telephone number given below for prompt action.

Respectfully submitted,



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